



[BILLING CODE 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed collection; 60-day comment request

The effectiveness of donor notification, HIV counseling, and linkage of HIV positive donors to health care in Brazil (NHLBI).

SUMMARY: In compliance with the requirement of Section 3506(c) (2) (A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Heart, Lung, and Blood Institute (NHLBI), the National Institutes of Health (NIH), will publish periodic summaries of proposed projects to the Office of Management and Budget (OMB) for review and approval.

Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are

to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

TO SUBMIT COMMENTS AND FOR FURTHER INFORMATION: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Simone Glynn, MD, Project Officer/ICD Contact, Two Rockledge Center, Suite 9142, 6701 Rockledge Drive, Bethesda, MD 20892, or call 301- 435-0065, or E-mail your request, including your address to: glynnsa@nhlbi.nih.gov. Formal requests for additional plans and instruments must be requested in writing.

COMMENT DUE DATE: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

PROPOSED COLLECTION: The effectiveness of donor notification, HIV counseling, and linkage of HIV positive donors to health care in Brazil (The Brazil Notification Study), 0925-New, National Heart, Lung and Blood Institute (NHLBI).

Need and Use of Information Collection: The prevention of transfusion-associated transmission of HIV is one of the greatest success stories in the fight against the HIV epidemic; however, the job is unfinished. In some middle-and low-income countries, blood transfusion may account for up to 6% of HIV infections (1). Currently, all blood donors who test positive or inconclusive for HIV or other sexually transmitted diseases are notified (donor notification) and requested to follow-up with the blood bank for potential confirmatory testing and referral to specific health services, such as monitoring and treatment. Little is known about the consequences of blood donor notification and subsequent monitoring and counseling on efforts

to control the HIV epidemic in the United States and internationally. The Brazil Notification Study team proposed to address this significant information gap by enrolling all former blood donors who participated in the REDS-II HIV case-control study (OMB 0925- 0597, expired on February 29, 2012) and those enrolled during the REDS-III HIV case surveillance risk factor study (OMB 0925-0597, expiration date, July 31, 2015), between 2012 and 2014. Donor enrollees at any of the four blood centers participating in these studies completed an audio computer-assisted structured interview (ACASI) that elicited responses on demographics, risk factors/behaviors, and HIV knowledge. At the same time, a blood sample was drawn and tested for HIV genotype and drug resistance. In addition, recent infection status was determined using detuned antibody testing of samples from the original blood donation. All enrolled participants received counseling by a blood bank physician and were referred to HIV counseling and testing centers (HCT).

New information gathered from these enrollees will serve the three aims proposed for this proposed study. The first aim of this study will be to analyze the actual percentage of blood donors who are successfully notified of their infection testing results. In this aim, we will expand the notification focus to include all infections that blood centers in Brazil test for because differences in rates of notification by type of infection are unknown. The second aim will assess the effectiveness of HIV notification and counseling. HIV-positive donors will be interviewed to evaluate their follow-up activities with regard to HIV infection treatment and infection transmission prevention behavior after notification by the blood center. This will be accomplished using a new audio computer-assisted structured interview (ACASI) (See Attachment 1, Brazil HIV Follow up ACASI Survey). The third aim will consist of asking HIV-positive blood donors about ways to improve the disclosure of HIV risks during donor eligibility

assessment to better understand the motivating factors that drive higher risk persons to donate blood.

Because our study will build off the routine blood donor procedures in four large blood banks in Brazil, it may lead to more informed conversations around and possible changes in donor screening, notification and counseling policies in Latin America. Results of these three aims may also help to better integrate blood centers within the context of broader HIV testing, counseling and treatment sites in Brazil. Similarly, in the US little is known about donor behavior after notification of testing results by blood centers. The results from this study can be used to develop insights and hypotheses focused on developing improved strategies for notification and counseling of HIV-positive (or hepatitis C or B-positive) donors in the U.S.

This proposed study's findings will also yield insights into improved methods for donor self-selection and qualification post donation, which will serve to decrease the frequency of higher-risk persons acting as donors. Our findings on improved methods for Brazilian donor notification and linkage to health care services may also be applicable to developed countries, including the US. Results of the Brazil Notification Study will identify how to improve notification and counseling strategies that increase the number of HIV-positive donors seeking prompt medical care. This might ultimately boost strategies to prevent secondary HIV transmission and reduce the risk of transfusion-transmission.

In addition to the traditional route of scientific dissemination through peer reviewed scientific publication, previous REDS and REDS-II study data were the subject of numerous requested presentations by Federal and non-Federal agencies, including the FDA Blood Products Advisory Committee, the HHS Advisory committee on Blood Safety and Availability, the AABB Transfusion-Transmitted Diseases Committee, and the Americas Blood Centers (ABC).

We anticipate similar requests for results generated from this study. Data collected in this proposed HIV Notification study of donors will be of practical use to the blood banking and infectious disease communities in the US and internationally.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 229.

Estimated Annualized Burden Hours

Form Name	Type of Respondent	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response	Estimated Total Annual Burden Hours Requested
ACASI Questionnaire - Informed Consent	Adults	275	1	10/60	46
ACASI Questionnaire	Adults	275	1	40/60	183

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Lynn Susulske,
NHLBI Project Clearance Liaison,
National Institutes of Health.

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